Attorney Docket No.: 601-017c1

IN THE UNTIED STATES PATENT AND TRADEMARK OFFICE

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In re application of
Zohoungbogbo et al. Examiner: Hui

Serial No: 09/982,554 Art unit: 1617

Filed: October 18, 2001

For: DIETETIC FOOD COMPOSITION
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APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs:

In response to the Office Action dated November 4, 2004 and further to the Notice of Appeal mailed on February 2, 2005, please enter the following Appeal Brief to be submitted to the Patent Board of Appeals and Interferences. A Petition for a Two - Month Extension of Time is enclosed herewith.

Also enclosed with this Appeal Brief is an Amendment After Final Rejection to make certain minor amendments to the claims before appeal.

Real Party in Interest

The real party in interest is Mr. Mathias Christian Zohoungbogbo.

Related Appeals and Interferences

The Appellant is not aware of any related prior or pending appeals or interferences related to this matter.

Status of Claims

Claims 45-56 are the pending claims in the application and are the claims on appeal.

Claim 50 is objected to because of the dosage of Metformin contained in the claim.

Claim 56 is objected to for a misspelling of the word "if." This has been addressed in the attached Amendment After Final Rejection.

Claims 48, 49, 53 and 54 stands rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. The amounts listed for the agents recited in these claims do not match those recited in the specification. This has been addressed in the attached Amendment After Final Rejection.

Claim 56 stands rejected under 35 U.S.C. § 112 for lack of sufficient antecedent basis for the limitation "the weight loss method" in the last line. This has been addressed in the attached Amendment After Final Rejection.

Claims 45, 47, 49-50, 52 and 54-56 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Marquie et al. (Life Sciences, 1998; 63(1):65-67), Pentikainen et al. (Annals of Medicine, 1990;22:307-312), and Poupon et al. (Heptology,

1993;17(4):577-582) in view of Spasmo-Canulase® Bitlab ® package insert (July 1989), and Krause et al. (Food Nutrition, and Therapy, 7th ed. 1984, page 656-658, W.B. Suanders Company).

Claims 46 and 51 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Marquie et al. (Life Sciences, 1998; 63(1):65-67), Pentikainen et al. (Annals of Medicine, 1990;22:307-312), and Poupon et al. (Heptology, 1993;17(4):577-582) in view of Spasmo-Canulase® Bitlab ® package insert (July 1989), and Krause et al. (Food Nutrition, and Therapy, 7th ed. 1984, page 656-658, W.B. Suanders Company) further in view of Hydrocotyle (A Modern Herbal Home Page, 1995), Kang et al. (Archives of Physiology and Biochemistry, 1997; 105(6):603-607), Pondimin monograph (PDR, 1996, page 2066-2067), and Keown et al. (WO/95/11034).

A copy of the Claims on Appeal is attached hereto in the Appendix of Claims, listing the current status of pending claims 45-56 claims as well as the status of now cancelled claims 1-44. It is noted that the claims in the attached Claims on Appeal reflect the changes made to claims 48, 49 and 56 in the accompanying Amendment After Final Rejection.

Status of Amendments

This application was originally filed on October 18, 2001 with 25 claims. A restriction requirement was issued on July 30, 2002. In response on September 30, 2002, Appellant elected to prosecute group III, namely the claims directed to treating a patient subjected to a ketogenic diet. At the same time, Appellant cancelled all 25 claims and submitted new claims 26-39 for review, all of which are directed to treating a patient subjected to a ketogenic diet.

On January 15, 2003, Appellant received the first Office Action on the merits. Claims 26-39 were rejected under 35 U.S.C. § 112 for technical reasons. Claims 26, 29, 30, 33 and 36-37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Marquie et al., Pentikainen et al., and Poupon et al. in view of Spasmo-Canulase® Bitlab ® package insert (July 1989). Claims 27, 28, 31-32, 34-35 and 38-39 are rejected as being unpatentable over Marquie et al., Pentikainen et al., Poupon et al., and Spasmo-Canulase® Bitlab ® package insert (July 1989), as applied to the above claims and further in view of Hydrocotyle, Kang et al., Pondimin monograph, and Keown et al.

In response, Appellant filed an Amendment on June 16, 2003, amending claims 26, 27, 29, 31 and 32 and adding new claim 40. Appellants amended claims 26, 27, 29, 31 and 32 to overcome the 35 U.S.C. § 112 rejections and submitted arguments that the prior art did not show the elements of the claimed invention. In support, Appellant

submitted a Declaration under 37 CFR 1.132 sign by the inventor.

A second and Final Office Action was issued on September 8, 2003. New claim 40 was withdrawn from consideration by constructive election because an Office Action on the merits had already been issued on the elected subject matter. The rejection of claims 32 and 39 (dependent) was continued under 35 U.S.C. § 112 because the Examiner did not allow the term "any tiroxine analogs." Claims 26, 29, 30, 33 and 36-37 were again rejected under 35 U.S.C. § 103(a) as being unpatentable over Marquie et al., Pentikainen et al., and Poupon et al. in view of Spasmo-Canulase® Bitlab ® package insert (July 1989). Claims 27, 28, 31-32, 34-35 and 38-39 are rejected as being unpatentable over Marquie et al., Pentikainen et al., Poupon et al., and Spasmo-Canulase® Bitlab ® package insert (July 1989), as applied to the above claims and further in view of Hydrocotyle, Kang et al., Pondimin monograph, and Keown et al.

In response, Appellant filed and RCE and Amendment on December 8, 2003, adding new claims 41-44 to pending claims 26-39.

On April 15, 2004, a third Office Action was mailed, withdrawing claims 26-39 and 41-43 by constructive election because an Office Action on the merits had already been issued on other elected subject matter. New claim 41 was now the base independent claim but contained a preamble directed to a food composition rather than a method for treating a patient on a ketogenic diet. Additionally, claim 44 was rejected under 35 U.S.C. § 112 for failing to be enabled by the specification.

Appellant responded on August 16, 2004, canceling all pending claims and resubmitting new claims 45-56. It is noted that new claim 45 corresponds to the subject matter of cancelled claims 44, 29 and 30. New claim 46 corresponds to cancelled claim 27. New claim 47 corresponds to cancelled claim 28. New claim 48 corresponds to cancelled claim 31. New claim 49 corresponds to cancelled claim 32. New claim 50 corresponds to cancelled claim 33. New claim 51 corresponds to cancelled claim 34. New claim 52 corresponds to cancelled claim 35. New claim 53 corresponds to cancelled claim 38. New claim 54 corresponds to cancelled claim 39. New claim 55 corresponds to cancelled claim 42. New claim 56 corresponds to cancelled claim 43.

In November 4, 2004, a fourth Office Action, the second to be issued as final, was issued on claims 45-56, leaving the claims as they stand as recited above section entitled "Status of Claims." A Notice of Appeal was filed by Appellants on February 2, 2005.

An Amendment After Final Rejection is filed concurrently herewith to make certain minor amendments to claims 48, 49 and 56.

Summary of the Invention

A ketogenic or low/no carbohydrate diet, although having some desired effects regarding weight control, may lead to an accumulation of lipids when feeding on foods that are essentially based on carbohydrates. (See Background, page 2, lines 18-25). The present invention is directed to a method for treating persons subjected to a ketogenic diet.

In particular the present invention calls for the treatment of persons subjected to a ketogenic diet by administering an agent having a number of components such as a hypocholesterolemic agent, including either benfluorex or ursodesoxycholic; a hypotriglyceride agent, benfluorex ; a lipasic and proteasic agent, pancreatin IX F.U.; a hypoglycemic agent, metformin; and a hydrocholeretic agent, including either Na dehydrocholate or ursodesoxycholic acid.

These and other additives to the compound may are discussed in detail in the detailed description portion of the specification on pages 8-11. As noted in page 15 lines 2-9 of the specification,

> "Said agents have been selected to be combined in a synergetic way such that to improve their single pharmaceutical properties and, at the same time, not interfering one with the others.
>
> The advantage provided by said pharmaceutical composition is that of preventing or treating the above mentioned side-effects which can occur in a diet lacking in carbohydrates."

Issues on Appeal

The first issue under rejection is claims 50-54 which call for a dosage of 7-23 grams for the compound. The Examiner states that when placed back into the dosages for metformin of 36%-41 by weight of the compound as recited in claim 45, it would have the metformin dosage at the daily maximum of 2500mg at the low end (36% of 7g) and higher thereafter. Appellant does not disagree, but requests that the Board instruct the Examiner to give leave to make this correction by amendment after ruling favorably on the merits of the remaining grounds for the Appeal.

The second issue on rejection is the objection to claim 56 based on the term "if'" misspelled as "is." Appellant has addressed this issue in the accompanying Amendment After Final Rejection. If Examiner accepts the Amendment, then this issue is settled, if not Appellant requests that the Board instruct the Examiner to give leave to make further corrections by amendment after ruling favorably on the merits of the remaining grounds for the Appeal.

The third issue on rejection is the rejection of claims 48, 49, 53 and 54 under 35 U.S.C. § 112 regarding the amounts of elements described not being supported by the specification. Appellant has addressed this issue in the accompanying Amendment After Final Rejection. If Examiner accepts the Amendment, then this issue is settled, if not Appellant requests that the Board instruct the Examiner to give leave to make further

corrections by amendment after ruling favorably on the merits of the remaining grounds for the Appeal.

The fourth issue on rejection is the rejection of claim 56 under 35 U.S.C. § 112 for the term "the weight loss method" not having proper antecedent basis. Appellant has addressed this issue in the accompanying Amendment After Final Rejection. If Examiner accepts the Amendment, then this issue is settled, if not Appellant requests that the Board instruct the Examiner to give leave to make further corrections by amendment after ruling favorably on the merits of the remaining grounds for the Appeal.

The fifth issue on rejection is the rejection of claims 45, 47, 49-50, 52 and 54-56 under 35 U.S.C. § 103. The Examiner contends that the subject matter of these claims are obvious over Marquie et al. (Life Sciences, 1998; 63(1):65-67), Pentikainen et al. (Annals of Medicine, 1990;22:307-312), and Poupon et al. (Heptology, 1993;17(4):577-582) in view of Spasmo-Canulase® Bitlab ® package insert (July 1989), and Krause et al. (Food Nutrition, and Therapy, 7th ed. 1984, page 656-658, W.B. Suanders Company).

Appellant respectfully disagrees with this contention and intends to demonstrate to the Board that the cited references do not teach or suggest all of the elements of the present invention as claimed in independent claim 45, nor is there any suggestion or motivation to combine the references with one another. Furthermore, it is not *prima facia* obvious to combine the reference under the law as set forth in *In re Kerkhoven* (205 USPQ 1069) as suggested by the Examiner.

The sixth issue on rejection is the rejection of claims 46, 51 under 35 U.S.C. § 103. The Examiner contends that the subject matter of these claims are obvious over Marquie et al. (Life Sciences, 1998; 63(1):65-67), Pentikainen et al. (Annals of Medicine, 1990;22:307-312), and Poupon et al. (Heptology, 1993;17(4):577-582) in view of Spasmo-Canulase® Bitlab ® package insert (July 1989), and Krause et al. (Food Nutrition, and Therapy, 7th ed. 1984, page 656-658, W.B. Suanders Company) as applied to claim 45, further in view of Hydrocotyle (A Modern Herbal Home Page, 1995), Kang et al. (Archives of Physiology and Biochemistry, 1997; 105(6):603-607), Pondimin monograph (PDR, 1996, page 2066-2067), and Keown et al. (WO/95/11034).

Appellant respectfully disagrees with these contentions and intends to demonstrate to the Board that the cited references do not teach or suggest all of the elements of the present invention as claimed in dependent claim 46 for the same reasons outlined above in support of independent claim 45. Furthermore, it is not *prima facia* obvious to combine the reference under the law as set forth in *In re Kerkhoven* (205 USPQ 1069) as suggested by the Examiner.

Arguments

There are two sets of arguments set forth below. The first set is in relation to independent claim 45, from which all other pending claims depend. The second set of arguments is in relation to dependent claim 46, from which claims 47, 48, 49, 51, 52, 53, 54 depend.

1st Argument - The cited prior art fails to teach or suggest all of the elements of independent claim 45. Therefore, the rejection of this claim should be withdrawn by the Board as well as the rejections to all of the claims that depend there from for at least the same reasons.

DETAILED DESCRIPTION OF APPELLANT'S INVENTION AS IT RELATED TO THE EXAMINER'S REJECTIONS

The present invention as claimed in independent claim 45 is directed to a method for treating persons subjected to a ketogenic diet so as to reduce the concentration of the body chemicals cholesterol, triglycerides, glicemia, uric acid, transaminases and fibrogen. The method includes the step of administering a composition of a plurality of agents.

The agents in the composition include a hypocholesterolemic agent, where the hypocholesterolemic agent is selected from the group consisting of benfluorex, which is present in the amount from 7% to 23% in weight of the total amount of the composition and ursodesoxycholic acid which is present in the amount from 14% to 17% in weight of the total amount of the composition.

Another agent in the composition is a hypotriglyceride agent, where the hypotriglyceride agent is benfluorex which is present in the amount of 7% to 23% in weight of the total amount of the composition.

A third agent in the composition being administered in a lipasic and proteasic agent, where the lipasic and proteasic agent is pancreatin IX F.U. which is present in the amount from 27% to 43% in weight of the total amount of the composition.

A fourth agent in the composition being administered is a hypoglycemic agent, where the hypoglycemic agent is metformin which is present in the amount of 36% to 41% in weight of the total amount of the composition.

A fifth agent in the composition being administered is a hydrocholeretic agent, where the hydrocholeretic agent is selected from the group consisting of Na dehydrocholate which is present in the amount from 9% to 14% in weight of the total amount of the composition, and ursodesoxycholic acid which is present in the amount from 14% to 17% in weight of the total amount of the composition.

In this arrangement, the present invention provides a method for treating persons subjected to a ketogenic diet by administering a single composition so as to reduce the concentration of the body chemicals cholesterol, triglycerides, glicemia, uric acid, transaminases and fibrogen.

As noted in the previously submitted amendments, the claimed agents have been selected to treat side effects of a ketogenic diet because they have a synergistic effect to improve their pharmaceutical properties and, at the same time, do not to interfere with the effectiveness of one another. See Specification page 15, paragraph 1.

As claimed and as noted in Example 8 on page 23 of the specification, the

claimed agents are mixed into a single composition (sealed capsule). In the Declaration dated June 16, 2003, submitted with the Amendment of the same date, the inventor Mr. Zohoungbogbo, stated that the administration of the composition from Example 8 to patients undergoing a ketogenic diet, such as a diet where carbohydrates have been effectively eliminated, maintained normal levels of cholesterol, triglycerides, glycemia, uric acid, transaminases and fibrinogen. A copy of Mr. Zohoungbogbo's declaration is attached in the Appendix of Evidence.

In the declaration on page 5, last paragraph, Mr. Zohoungbogbo further states:

> "In fact, it is well known to the physicians that drugs available on the market are composed of at most two kinds of active ingredients. Nobody has demonstrated a surprising synergic effect of a composition as the one of my invention comprising more than two active ingredients."

This invention provides two inventive steps over the prior art. First it combines a series of active agents into a single composition in such quantities to bring about an overall desired effect of reducing at least six internal body chemical factors to within normal range, even when a patient is undergoing a ketogenic diet while simultaneously not negatively interacting with one another. Secondly, the claimed method brings an additional advantage of assisting patients who have to take a great number of drugs throughout the day, by condensing to a single composition.

On a separate note, as indicated on page 13 of the specification, pancreatin IX F.U. is total lyophilized pancreas, used in the treatment of pancreatic insufficiency and sodium dehydrocholate is a hydrocholeretic agent which causes low-density biliary secretion.

EXAMINER'S ARGUMENT'S AGAINST INDEPENDENT CLAIM 45

The Examiner has issued arguments in the Office Actions, including the latest Office Action dated November 4, 2004, that the cited prior art, when combined with one another teach or suggest all of the elements of independent claim 45.

The Examiner states that Marquie teaches using benfluorex for treating hypercholesterolemia, that Pentikain teaches using metformin to lower cholesterol and Poupon teaches using ursodesoxycholic acid to treat hypercholesterolemia.

The Examine then continues by stating that

"the references do not expressly teach the method of treating the side effects of a ketogenic diet with the combination of benfluorex, metformin, and ursodesoxycholic acid. The references do not expressly teach the herein claimed amount ratio employed. The references do not expressly teach the employment of pancreatin and sodium dehydrocholate with benfluorex and metformin. The references do not expressly teach the dosage of the composition herein claimed as 7g to 23g. The references do not expressly teach the method further include steps that replace the food composition in form of a flour having more that 20% carbohydrates by weight and determine the patients whether is suffering from the side effects of ketogenic diet [sic]

Spasmo-Canulase Bitab package insert teaches Spasmo-Canulase Bitab which contains pancreatin and sodium dehydrocholate, is useful in treating abdominal cramps associated with flatulence. [sic]

Krause et al teaches ketogenic diet as approximately 90% of calories are from fat and only around 11% of calories are from proteins and carbohydrates (page 657, col. 1-2) [sic]

The Examiner goes on to state that it would have been obvious to combine the teachings of these five references to arrive at the present invention as claimed in independent claim 45.

APPELLANT'S RESPONSE AND ARGUMENT FOR WITHDRAWL OF THE EXAMINER'S REJECTION BY THE PATENT BOARD OF APPEALS AND INTERFERENCES

The cited prior art, used by the Examiner to form the basis of the rejection contain no teaching or suggestion to combine themselves with one another as required to form a rejection under 35 USC 103(a). Furthermore, the elements of independent claims 45 are not *prima facia* obvious in view of the prior art under the law set forth in *In re Kerkhoven* (205 USPQ 1069).

Beginning with the cited prior art, the Marquie reference, teaches the use of benfluorex to decrease glucose intolerance, hyperinsulinemia, hypertryglyceridemia, hypercholesterolemia and plasma LDL- and VLDL-cholesterol as set forth in the abstract. The Marquie reference deals only with the use of benfluorex alone in treating the researched factors, as shown in page 71, indicating that benfluorex was effective after about 3 months in reducing certain internal levels of harmful elements.

The Pentikain reference teaches the use of metformin to lower cholesterol in patients. Pentikain reference tests the metformin against a placebo but does not teach the use of metformin in combination with any other agent.

The Poupon reference teaches a study showing the cholesterol lowering effect of ursodesoxycholic acid. In the abstract, it is noted that "[n]o significant change occurred in total triglyceride or total phospholipid levels."

The spasmo-canulase reference simply teaches the administration of multi-

element compound including Na dehydrocholate and pancreatin for treating abdominal cramps, associated with flatulence.

Lastly the Krause reference simply discloses that a ketogenic diet involves increasing the % of calories from fat and significantly decreasing the % of calories from carbohydrates.

As noted above, the Examiner is essentially arguing that each of the references alone teaches the treatment of a condition by way of a particular agent, and that it is *prima facia* obvious to combine the references as set forth in *Kerkhoven* into a single method for the same purpose (treating a ketogenic diet).

Appellant disagree with this contention.

First, the Examiner states that abdominal cramps and flatulence are common side effects of metformin and hence it would be obvious to combine the first three elements with the Spasmo-canulase to add the pancreatin and sodium dehydrocholate and arrive at the present invention as claimed.

However, the as noted above, the pancreatin IX F.U. and sodium hydrocholate is added not to treat flatulence or cramps, but to treat insufficient pancreas function and to induce low-density biliary secretion.

There is no teaching or suggestion to use the teachings of the Spasmo-canulase reference to treat the side effects of a ketogenic diet, namely insufficient pancreas function, and further to induce low-density biliary secretion. As such, the use of a cramp or flatulence reducing agent may not even be required at all unless the particular patient is experiencing such effects, whereas the present invention positively recites the

pancreatin in every instance as it is a positively recited element.

Secondly, it is acknowledged by the Examiner, none of the references teach the exact amounts of the various components as claimed in independent claim 45. The Examiner has stated that the results effect parameters are obvious and within the skill of the artisan.

However, as noted above, and in the declaration of the inventor, the claimed ratios set forth of components in the administered compound are measured such that they both have the desired effects, and even when combined, do not effect one another detrimentally through unwanted interaction as is shown on the accompanying table in the declaration. Further to this, it is known in the field of medicine that combinations of agents may greatly affect the efficacy of one another. As such, although adjusting the dosage of a single agent may be within the skill of an artisan, it is not within the skill of the artisan to set dosages of a number of combined elements to achieve a particular effect nor is it in the regular skill of an artisan to set the dosages such that the agents do not deleteriously affect one another or the patient to which they are being administered.

Third, and most importantly, the Examiner has not established a *prima facia* case of obviousness because there is no suggestion or motivation in any of the references that suggest combining the teachings of any one of them with one another. Instead, the Examiner errantly relies on the *Kerkhoven* reference stating that each of the references independently teaches its use for a particular condition, and that is it is therefore obvious to combine all of the elements of claim 45 and also obvious to set the dosages with one

another even when there is no such suggestion in the prior art.

To establish a prima facie case of obviousness the Examiner must show the following steps:

1) set forth the differences in the claim over the applied reference;

2) set forth the proposed modifications of the references which would be necessary to arrive at the claimed subject matter; and

3) explain why the proposed modification would be obvious.

To satisfy step (3), the Examiner must identify where the prior art provides a motivating suggestion to make the modifications proposed in step (2), *In re Jones*, 958 F.2d 347, 21 U.S.P.Q. 2d 1941 (Fed Cir. 1992).

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absents some teaching or suggestion or incentive to combine them, *In re Bond*, 910 F.2d 831, 834; 15 U.S.P.Q. 2d 1566, 1568 (Fed Cir. 1990). With respect to the pending claims in the present application, the references cited by the Examiner fail to provide any teaching or suggestion to combine the pancreatin IX F.U., sodium dehydrocholate, benfluorex, metformin and ursodesoxycholic acid, in the claimed ratios as done in independent claim 45.

In the medical field, combining certain agents with one another is widely known to show potential for deleterious effects. As such, the combination of particular agents in particular ratios is not a matter of simply picking and choosing them from the shelf as suggested by the Examiner.

For example, in the claimed invention, the various agents are combined in manner

to treat the side effects of a ketogenic diet, having the results shown in the declaration, normalizing the level of a number of internal body chemicals to within their normal range. Two of the agents include pancreatin IX F.U. and sodium dehydrocholate. The overall effect of those combined agents as claimed results in a lowering of bodily chemicals other than just cholesterol and triglycerides, such as fibrogen, elevated levels of which also result from a ketogenic diet.

As noted by the Examiner, benfluorex, metformin and ursodesoxycholic acid are each used to treat hypercholesterolemia. However, none of these references, which contain teachings for using these agents, also contain a suggestion to combine them with one another or to combine them with pancreatin or a sodium dehydrocholate agent to help further stabilize other internal body chemicals which are affected by a ketogenic diet. The Examiner has not indicated why a person taking a first hypercholesterolemia agent would look to a second or third, let alone citing a reference to such an affect.

Furthermore, regarding the combination with spasmo-canulase, the Examiner simply states that one of the agents, metformin, has a side effect of cramps, and that it would be obvious to combine the spasmo-canulase to address this issue.

However, none of the references suggest such a combination. Furthermore, such a combination under those circumstances would not even be necessary should a patient not suffer from such side effects by the metformin. In such an instance of no-cramps or no-flatulence, there would be no need to combine the spasmo-canulase to the other agents. Simply because a particular side effect may be experienced in certain limited situations does not obviate the need to add both pancreatin and sodium dehydrocholate to additional hypercholesterolemic agents in every instance, such as claimed in the present

invention in claim 45. Furthermore, it is noted that the spasmo-canulase reference makes no mention of its use in connection with treating side effects of a ketogenic diet nor does it mention its use in connection with any one of benfluorex, metformin, or ursodesoxycholic acid.

In the Appellant's opinion, it appears that the Examiner is using the Appellants claim as a blue print and picking and choosing references to address the elements singularly in the abstract apart from the claim as whole, contrary to the requirement of 35 U.S.C. § 103 (a) rejection.

Appellant is aware of the *Kerkhoven* case, but argues that it does not apply in this case as it is not obvious in the field of medical compounds to simply pick and choose when combining agents for treating a condition. Much to the contrary in the medical field, combining certain agents with one another is widely known to show potential for deleterious effects.

In the matter of *In re Geiger* (2 U.S.P.Q.2d 1276) the U.S. Court of Appeals for the Federal Circuit held that the standard for obviousness was not met where the application was based on a specific combination of existing techniques ***where many possible combinations existed***. The court sides with the Applicant noting that the Examiner can not use hind sight reconstruction and that at best it would have been "obvious to try" various combinations of known agents including those recited by the Applicant.

In the present case, the Examiner, at best, has made an argument that to treat the side effects of a ketogenic it would have ***been obvious to try*** a number of combinations which may or may not include the present invention as claimed. However, this is not the

standard for an obvious rejection. Rather, the Examiner must establish that ***this particular combination as claimed by Appellant is obvious***. No such teaching or suggestion is sited to, nor is it generally obvious in the field of medicine agents to simply pull random agents with individual known affects and combine them to treat a particular condition (side effects of a ketogenic diet).

As such, Appellants submits that the cited prior art fails to teach or suggest the present invention as claimed in claim 45, and respectfully request that the Patent Board of Appeals and Interferences, reverse the 35 U.S.C. § 103(a) rejection of this claim. Likewise, as all claims 46-56 depend there from, the rejections of these claims should be withdrawn for at least the same reasons.

2nd Argument - The cited prior art fails to teach or suggest all of the elements of dependent claim 46. Therefore, the rejection of this claim should be withdrawn by the Board as well as the rejection to all of the claims that depend there from for at least the same reasons.

DETAILED DESCRIPTION OF APPELLANT'S INVENTION AS IT RELATED TO THE EXAMINER'S REJECTIONS

The present invention as claimed in dependent claim 46 is directed to the method as claimed in claim 45, and further includes the steps of administering any one of a hypouricemic agent, where the hypouricemic agent is centella asiatica purified triterpenes; a radical scavenger agent, where the radical scavenger agent is selenium; a sympatholytic agent, where the sympatholytic agent is yohimbine; a sympathicomimetic

agent, where the sympathicomimetic agent is from the group consisting of phendimetrazine bitartrate and phendimetrazinum pamoate; and at least one vitamin, where the at least on vitamin being selected from the group consisting of vitamin A, vitamin B1, vitamin B6, vitamin E and Vitamin C.

EXAMINER'S ARGUMENT'S AGAINST INDEPENDENT CLAIM 46

The Examiner has rejected this claim under similar grounds for that set forth against the parent claims, further citing to the references: Hydrocotyle (A Modern Herbal Home Page, 1995), Kang et al. (Archives of Physiology and Biochemistry, 1997; 105(6):603-607), Pondimin monograph (PDR, 1996, page 2066-2067), and Keown et al. (WO/95/11034).

APPELLANT'S RESPONSE AND ARGUMENT FOR WITHDRAWL OF THE EXAMINER'S REJECTION BY THE PATENT BOARD OF APPEALS AND INTERFERENCES

Appellants note that the additional cited reference Hydrocotyle, teaches that hydroccotyle asiatica acts as a mild stimulant. The Kang reference teaches the use of selenium to decrease NOS (Nitric Oxcide Synthase) activity (page 604, second sentence of discussion). Neither reference teaches its combination with other components to reduce the effect of a ketogenic diet.

The Pondimin reference teaches that fenfluramine is a sympathomimetic amine (anoretic) which acts primarily as an appetite suppressant. Although it mentions that

blood glucose levels were reduced, it indicates that the mechanism of operation is not clear. Furthermore, it contains no indication of synergistic effect when used in combination with other compounds.

The Keown reference teaches a weight reduction composition that produces significant weight over a period of time and is safe, lacking the disadvantage of protein loss. The composition comprises two substances, a sympathomimetic agent and a salt or chelate mineral. The two substances provide an anoretic effect and normalize insulin level in the blood (Page 8, lines 27-28).

None of these references maintain any suggestion or motivation to combine themselves with the hypocholesterolemic agent, a hypotriglyceride agent, a lipasic and proteasic agent, a hypoglycemic agent, and a hydrocholeretic agent, as claimed in claim 45.

Thus, in line with the same arguments set forth above, Appellant argues again that the Examiner can not use the claim as a blueprint for uncovering references, but rather needs to cite a reference suggesting their combination with one another. Assuming arguendo that the above comments regarding claim 45 are correct, Appellants assert that it is even further not obvious to combine all of the elements of claim 45 with yet another element selected from those listed in claim 45. Again the Examiner has simply selected references that teach the compounds shown in the claim elements without actually pointing to a suggestion or motivation to combine those references with the five agents listed in claim 45.

As such, Appellants submit that the cited prior art fails to teach or suggest the present invention as claimed in claim 46, and respectfully request that the Patent Board of

Appeals and Interferences, reverse the 35 U.S.C. § 103(a) rejection of this claim. Likewise, as claims 47, 48, 49, 51, 52, 53, 54 depend there from, the rejections of these claims should be withdrawn for at least the same reasons.

Conclusion

In view of the forgoing, Appellant respectfully submits that the present invention as claimed is now in condition for allowance, and requests that the Patent Board of Appeals reverses the rejections of the Examiner and remands it to him for further prosecution as requested by Appellant.

Respectfully submitted

SOFER & HAROUN, LLP

Dated: 6/2/05

By: _____

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CLAIMS ON APPEAL

1-44. (cancelled)

45. (rejected) A method for treating persons subjected to a ketogenic diet, so as to reduce the concentration of the body chemicals cholesterol, triglycerides, glicemia, uric acid, transaminases and fibrogen said method comprising the step of:

administering a composition of a plurality of agents including;

a hypocholesterolemic agent, wherein said hypocholesterolemic agent is selected from the group consisting of benfluorex, which is present in the amount from 7% to 23% in weight of the total amount of the composition and ursodesoxycholic acid which is present in the amount from 14% to 17% in weight of the total amount of the composition;

a hypotriglyceride agent, wherein said hypotriglyceride agent is benfluorex which is present in the amount of 7% to 23% in weight of the total amount of the composition;

a lipasic and proteasic agent, wherein said lipasic and proteasic agent is pancreatin IX F.U. which is present in the amount from 27% to 43% in weight of the total amount of the composition;

a hypoglycemic agent, wherein said hypoglycemic agent is metformin which is present in the amount of 36% to 41% in weight of the total amount of the composition; and

a hydrocholeretic agent, wherein said hydrocholeretic agent is selected from the group consisting of Na dehydrocholate which is present in the amount from 9% to 14% in

weight of the total amount of the composition and ursodesoxycholic acid which is present in the amount from 14% to 17% in weight of the total amount of the composition.

46. (rejected) The method as claimed in claim 45, wherein in said administration of said composition, said composition further comprises at least one of:

a hypouricemic agent, wherein said hypouricemic agent is centella asiatica purified triterpenes;

a radical scavenger agent, wherein said radical scavenger agent is selenium;

a sympatholytic agent, wherein said sympatholytic agent is yohimbine;

a sympathicomimetic agent, wherein said sympathicomimetic agent is from the group consisting of phendimetrazine bitartrate and phendimetrazinum pamoate; and

at least one vitamin, wherein said at least on vitamin being selected from the group consisting of vitamin A, vitamin B1, vitamin B6, vitamin E and Vitamin C.

47. (rejected) The method as claimed in claim 46, wherein in said administration of said composition, said composition further comprises at least one diet adjuvant selected from the group consisting of sedative-ansiolytic agents, anoretic agents and lipolytic agents.

48. (rejected) The method as claimed in claim 46, wherein in said administration of said composition, each of said elements of said composition are in a

ratio of weight with respect to the total weight of said composition wherein,

said centella asiatica purified triterpenes is in a ratio from 0.04:1 to 0.5:1 in weight with respect to said total weight of composition;

said selenium is in a ratio from 0.0001:1 to 0.0003:1 in weight with respect to said total weight of composition;

said yohimbine is in a ratio from 0.0009:1 to 0.0007:1 in weight with respect to said total weight of composition;

said phendimetrazine bitartarate or phendimetrazine pamoate is in a ratio from 0.004:1 to 0.1:1 in weight with respect to said total weight of composition;

said vitamin A is in a ratio from 0.4:1 to 1.8:1 in weight with respect to said total weight of composition;

said vitamin B1, is in a ratio from 0.002:1 to 0.0007:1 in weight with respect to said total weight of composition;

said vitamin B6, is in a ratio from 0.04:1 to 0.2:1 in weight with respect to said total weight of composition;

said vitamin E, is in a ratio from 0.09:1 to 1:1 in weight with respect to said total weight of composition; and

said vitamin C, is in a ratio from 0.09:1 to 0.3:1 in weight with respect to the total weight of composition.

49. (rejected) The method as claim in claim 47, wherein in said administration of said composition, each of said elements of said composition are in a ratio of weight with respect to the total weight of the composition wherein ;

said sedative-ansiolityc agent is the benzodiazepine dipotassium chlorazepate in a ratio from 0.0004:1 to 0.03:1 in weight with respect to the total weight of composition;

said anoretic agent is selected from the group consisting of diethylpropione chlorhydrate, fenfluramine chlorhydrate, D-fenfluramine chlorhydrate, said anorectic agent being present in a ratio from 0.002:1 to 0.1:1 in weight with respect to said total weight of composition; and

said lipolityc agent is triiodiotiroacetic acid which is present in a ratio from 0.0002:1 to 0.003:1 in weight with respect to said total weigh of composition.

50. (rejected) The method as claimed in claim 45, wherein said administration of said composition is performed orally in doses from 7g to 23g per day to a patient of the weight of approximately 70kg.

51. (rejected) The method as claimed in claim 46, wherein said administration of said composition is performed orally in doses from 7g to 23g per day to a patient of the weight of approximately 70kg.

52. (rejected) The method as claimed in claim 47, wherein said administration of said composition is performed orally in doses from 7g to 23g per day to a patient of the weight of approximately 70kg.

53. (rejected) The method as claimed in claim 48, wherein said administration

of said composition is performed orally in doses from 7g to 23g per day to a patient of the weight of approximately 70kg.

54. (rejected) The method as claimed in claim 49, wherein said administration of said composition is performed orally in doses from 7g to 23g per day to a patient of the weight of approximately 70kg.

55. (rejected) The method according to claim 45, wherein said method further comprises the step of after reducing or eliminating all carbohydrate-based foods, replacing said carbohydrate-based foods with foods obtained using a food composition in the form of a flour having no more than 20% carbohydrates by weight.

56. (rejected) The method according to claim 55, wherein said method further comprises the step of, after replacing said carbohydrate-based foods with foods obtained using a food composition in the form of a flour having no more than 20% carbohydrates by weight, determining if said person is suffering from effects from the reducing or eliminating all carbohydrate-based foods, and replacing said carbohydrate-based foods with foods obtained using a food composition in the form of a flour having no more than 20% carbohydrates by weight.